

REMARKS/ARGUMENTS

I. Introduction

- Claims 1, 3-5, 7-13, 15-17, 26 and 31 are pending in the application.
- Claims 1, 12, 13, 16, 26, and 31 are the only independent claims under review.
- Claims 1, 3, 4, 7-13, 15-17, 26 and 31 are objected to.
- Claims 1, 3-5, 7-13, 15-17, 26 are rejected under 35 U.S.C. 112, first paragraph.
- Claims 1, 3-5, 7-13, 15-17, and 31 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Vilsmeier et al. (US 6,611,700) in view of Ferre et al. (US 5,967,980).
- The following comments will be made with reference to the published Patent Application for this case, United States Patent Application Publication No.: US 2002/0087101 A1.

II. Claim Objections

Claims 1, 3, 4, 8-13, 15-17, and 26 are objected to for using the terms "non-invasive" and "external curvature data". Specifically, the Examiner requested Applicant "to clarify and to provide support from the specifications." As shown in examples throughout the specification, the term "non-invasive" is meant to add the limitation to the claims that the

curvature sensor does not invade the patient. That is, the sensor is used externally (not internally) to a patients body.

Support for the term non-invasive may be found in paragraph [0074] which states that “a non-invasive alternative to registration methods, ... a ... curvature sensor may be affixed to a patient's skin, either adhesively or embedded in a garment, bandage, tape or other structure.” Additional support for the term “non-invasive” is found in paragraph [0086] of the specification which describes various embodiments of the invention as being non-invasive.

Applicants believe that there is ample support for the phrase “**external curvature data**”. Consider the following parsing tree for the term “external curvature data”:

1. The term “external” is a modifier for the term “curvature”.
2. The term “external curvature” is a modifier for the term “data.”

The term external means “of, relating to, or connected with the outside or an outer part ... applied or applicable to the outside.” The Merriam-Webster’s Collegiate Dictionary 412 (10th ed. 1993). The term curvature means “a measure or amount or curving.” The Merriam-Webster’s Collegiate Dictionary 285 (10th ed. 1993). The term “data” means “information output by a sensing device.” The Merriam-Webster’s Collegiate Dictionary 293 (10th ed. 1993). Therefore, applying the modifiers

to the term “data” yields “***information output by a sensing device***”, “***a measure or amount or curving***”, “***relating to, or connected with the outside or an outer part***”.

Support for the term “**external curvature data**” as defined above may be found in numerous references throughout the drawings that show the curvature sensors (that generate data) externally affixed to patient(s).

FIGURE 1 shows curvature sensor 100 applied externally to human head 110.” *See paragraph [0049].* FIGURE 4 shows “curvature sensors 410 ... forming a cap on a head 440.” *See paragraph [0052].* FIGURE 5 shows “curvature sensors 410 ... forming a pants-like garment” fitted externally to a patient. *See paragraph [0053].* FIGURE 6 shows a “curvature sensor 100 ... applied [externally] with adhesive to the thigh 605.” *See paragraph [0054].*

Additional support for the term “external curvature data” may be found in numerous references throughout the specification that describe external curvature sensors (that generate data). For example, paragraphs [0017], [0023], and [0026] describe a “curvature sensor configured to be placed on the Patient.” Paragraphs [0022], [0024], [0026], [0043] and [0053] describe the curvature sensor(s) being used to create a garment to be worn by a patient [external to their body]. Paragraph [0036] discloses curvature sensors ... applied to the skin of a patient to electronically measure ... the

precise contour of a portion of the patient's body and provide this three-dimensional surface contour data. Paragraph [0046] discloses a curvature sensor device fixed in place (such as with adhesive) on the object portion of the patient's body ... in the form of a strip, tape, band or mesh ... that can be laid upon or wrapped about the patient in the area where surgery is to be performed. . Paragraph [0054] discloses a "curvature sensor 100 ..." applied with adhesive to the thigh." Paragraph [00684] discloses a "curvature sensor ... attached to the surface of the patient." Paragraph [0070] discloses a "curvature sensor ... adhered to the skin surface." Applicant wished to point out that these are not all of the references that support the curvature sensor being external. In fact, there are zero references to any curvature sensor that is used internally.

Therefore, because there is support for the terms "non-invasive" and "external curvature data," Applicant respectfully requests that these objections be withdrawn.

The Examiner also requested Applicant correct the strikethrough phrase "computer readable" in the last paragraph of amended Claim 1 because it was not previously presented. Applicant submits that this phrase was a typographical error on behalf of Applicant in the previous Amendment. Applicant is unsure how to make the correction requested by the examiner since the phrase was never in the claim. However, Applicant would like to

point out to the Examiner that the phrase is not included in the current set of claims.

III. Claim Rejections under 35 U.S.C. § 112

Claims 1, 3-5, 7-13, 15-17, and 26 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner stated that “[t]he claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner stated that the phrase "external curvature data" is new matter.

For the reasons described in section II of this REMARKS/ARGUMENTS section, Applicant believes that "external curvature data" is described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Therefore, Applicant respectfully requests withdrawal of these rejections.

IV. Claim Rejections under 35 U.S.C. § 103

Claims 1, 3-5, 7-13, 15-17, and 31 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Vilsmeier et al. (US 6,611,700) in view of Ferre et al. (US 5,967,980).

A. The rejections under 35 U.S.C. 103(a) are improper because the Examiner did not examine the proper claims

Applicant is confused by the Examiners rejections because the rejections appear to not address the current claims. Additionally, the majority of the rejections for all of the claims are combined into a single sentence paragraph without any indication which clauses correlate to which claims. Many of the clauses in the single sentence paragraph appear to be modified, have words added, sections removed, reordered, and taken out of context. Applicant would like to present some of the clauses in question.

1. Applicant believes that the following phase cited by the Examiner on pages 3 and 4 of the Office Action is supposed to be from Claim 1:

a device for performing surgery or therapeutic interventions on a patient, comprising: a first curvature sensor configured to be placed externally on a patient, the first curvature

sensor providing an output readable by a computer; an attachment fixture coupled to the curvature sensor, wherein the computer is configured to receive the output of the curvature sensor.

However, the most similar clause from Claim 1 as presented in our response dated October 5, 2006 would have to be modified as shown below to get the clause shown above.

[a] device for performing surgery or therapeutic interventions on a patient, comprising: a first **non-invasive** curvature sensor configured to be placed externally on a patient, the first **non-invasive** curvature sensor providing **first external curvature data an output readable by a computer; imageable fiducials coupled to the first non-invasive curvature sensor;** **and** an attachment fixture coupled to the **first non-invasive** curvature sensor; **and wherein a the** computer **is** configured to receive **the first external curvature data and relate the curvature of the first non-invasive the output of the** curvature sensor **to the location of the imageable fiducials.**

2. Applicant believes that the following phase cited by the Examiner on page 4 of the Office Action is supposed to be from Claim 3:

a second curvature sensor providing an output to the computer, the second curvature sensor having a first end and a second end and capable of being coupled to the attachment fixture at the first end; and a tool connector coupled to the second end of the second curvature sensor,

However, the most similar clause from Claim 3 as presented in our response dated October 5, 2006 would have to be modified as shown below to get the clause shown above.

a second *non-invasive* curvature sensor providing *second external curvature data an output readable by the computer*, the second *non-invasive* curvature sensor having a first end and a second end and capable of being coupled to the attachment fixture at the first end; and a tool connector coupled to the second end of the second *non-invasive* curvature sensor.

3. Applicant believes that the following phrase cited by the Examiner on page 4 of the Office Action is supposed to be from Claim 4:

a second attachment fixture capable of being positioned at a known location with respect to the first curvature sensor, wherein the second end of the second curvature sensor is coupled to the second attachment fixture and the tool connector is coupled to the second curvature sensor between the first end and the second end,

However, the most similar clause from Claim 4 as presented in our response dated October 5, 2006 would have to be modified as shown below to get the clause shown above.

a second attachment fixture capable of being positioned at a known location with respect to the first **non-invasive** curvature sensor, wherein the second end of the second **non-invasive** curvature sensor is coupled to the second attachment fixture and the tool connector is coupled to the second **non-invasive** curvature sensor between the first

end and the second end.

4. Applicant believes that the following phase cited by the Examiner on page 4 of the Office Action is supposed to be from Claim 8:

wherein the computer uses both the second curvature sensor and the optical tracking system to positionally track the tool connector or a tool positioned in the tool connector,

However, the most similar clause from Claim 8 as presented in our response dated October 5, 2006 would have to be modified as shown below to get the clause shown above.

wherein the computer uses both the second **non-invasive** curvature sensor and the optical tracking system to positionally track the tool connector or a tool positioned in the tool connector.

5. Applicant believes that the following phase cited by the Examiner on page 4 of the Office Action is supposed to be from Claim 9:

wherein the computer is configured to determine an attachment fixture-centered

frame of reference based on the output of the curvature sensor,

However, the most similar clause from Claim 9 as presented in our response dated October 5, 2006 would have to be modified as shown below to get the clause shown above.

wherein the computer is configured to determine an attachment fixture-centered frame of reference based on the **first external curvature data output of the curvature sensor.**

6. Applicant believes that the following phase cited by the Examiner on page 4 of the Office Action is supposed to be from Claim 10:

wherein the attachment fixture comprises a latching mechanism configured for attaching to the first end of the second curvature sensor.

However, the most similar clause from Claim 10 as presented in our response dated October 5, 2006 would have to be modified as shown below to get the clause shown above.

wherein the first **non-invasive** curvature sensor comprises a fiber optic curvature sensor.

7. Applicant believes that the following phrase cited by the Examiner on page 4 of the Office Action is supposed to be from either Claim 13 or 16.

the curvature sensor being configured to provide an output of the curvature the portion of the patient.

However, the most similar clause from Claim 13 as presented in our response dated October 5, 2006 would have to be modified as shown below to get the clause shown above.

a non-invasive curvature sensor configured to be applied externally to a portion of a patient, the non-invasive curvature sensor being adapted to measure and provide external curvature data a computer readable output of the curvature the portion of the patient to a computer

Additionally, the most similar clause from Claim 16 as presented in our response dated October 5, 2006 would have to be modified as shown below to get the clause shown above.

a non-invasive curvature sensor configured to be applied externally to a portion of a patient,

the non-invasive curvature sensor being adapted to measure and provide external curvature data ~~an output readable by a computer~~ of the curvature of the portion of the patient;

8. Applicant believes that the following phase cited by the Examiner on page 5 of the Office Action is supposed to be from Claim 16

a device for generating a patient-based frame of reference for an image guided therapy or image guided surgery system.

However, the most similar clause from Claim 16 as presented in our response dated October 5, 2006 would have to be modified as shown below to get the clause shown above.

[a] device for generating a patient based frame of reference for an image guided therapy or image guided surgery system.

9. Applicant believes that the following phase cited by the Examiner on page 5 of the Office Action is supposed to be from Claim 26

a tool capable of being coupled to the second

end of the second curvature sensor.

However, the most similar clause from Claim 26 as presented in our response dated October 5, 2006 would have to be modified as shown below to get the clause shown above.

... a tool capable of being coupled to the second end of the second **non-invasive** curvature sensor

11. Applicant believes that the following phrase cited by the Examiner on page 5 of the Office Action is supposed to be from Claims 1, 12, 13, 16, or 26.

and wherein the computer is configured to relate the curvature of the first curvature sensor to the location of the fiducials.

However, the most similar clause from Claim 1 as presented in our response dated October 5, 2006 would have to be modified as shown below to get the clause shown above.

... ~~wherein the a~~ computer **[[is]]** configured to ~~receive the first external curvature data and~~ relate the curvature of the first **non-invasive** curvature sensor to the location of the imageable fiducials.

The most similar clause from Claims 12, 13, and 16 as presented in our response dated October 5, 2006 would have to be modified as shown below to get the clause shown above.

.. ~~wherein the a~~ computer *[[is]]* configured to
receive the external curvature data and
relate the curvature of the first *non-invasive*
curvature sensor to the location of the
imageable fiducials.

However, the most similar clause from Claim 26 as presented in our response dated October 5, 2006 would have to be modified as shown below to get the clause shown above.

~~wherein the a~~ computer *[[is]]* configured to:
receive the first external curvature data;
receive the second external curvature data;
relate the curvature of the first *non-invasive*
curvature sensor to the location of the
imageable fiducials;

12. Applicant believes that the following phase cited by the Examiner on page 5 of the Office Action is supposed to be from Claim 26

a communication device electronically coupled

to the computer

However, the most similar clause from Claim 1 as presented in our response dated October 5, 2006 would have to be modified as shown below to get the clause shown above.

***communicate the output of the computer to
a distant receiver using a*** communication device that is electronically coupled to the computer.

Therefore, because the rejections under 35 U.S.C. 103(a) were not directed to the proper claims, Applicant respectfully requests that these rejections be withdrawn.

B. The rejections under 35 U.S.C. 103(a) are improper because the sensor in Ferre et al (US 5,676,673) is not equivalent to the sensor in the presently claimed application.

There are many types of sensors. Examples include thermal sensors, electromagnetic sensors, mechanical sensors, chemical sensors, optical radiation sensors, ionizing radiation sensors, acoustic sensors, motion sensors, orientation sensors, distance sensors, etc. Many of these sensors are significantly different from each other and cannot be exchanged with sensors from differing

systems without making those systems inoperable. Such is the case with the non-invasive curvature sensor claimed in the present invention and the sensor discussed in the abstract of Ferre.

The Examiner points to the abstract of Ferre to show that Ferre discloses "a sensor providing an output readable by a computer." See Office Action, page 5. First, the phrase "a sensor providing an output readable by a computer" is not claimed in the current set of claims. Therefore, this Applicant believes that this reference is improper.

Second, the sensor referenced in the abstract does not provide "an output readable by a computer." The abstract describes a "sensor output signal" that produces "position information" (NOT curvature data). The position information is for a single point. The non-invasive curvature sensor in the currently claimed invention provides multi-point curvature data in some embodiments and full surface data in other embodiments.

Therefore, because the sensor in Ferre et al (US 5,676,673) is not equivalent to the sensor in the presently claimed application, Applicant respectfully requests that these rejections be withdrawn.

V. Conclusion

The Commissioner is hereby authorized to charge any additional fees, which may be required, or credit any overpayment, to Deposit Account No. 50-3212.

In the event that an extension of time is required, or may be required in addition to that requested in a petition for an extension for time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 50-3212.

Respectfully submitted,

/David G. Grossman, Reg. No. 42,609/

David G. Grossman
Registration No. 42,609

Date: May 25, 2007

George Mason University
Office of Technology Transfer, MSN 5G5
4400 University Drive
Fairfax, VA 22030
Phone: (703) 338-6333